

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF OREGON**

**UNITED STATES OF AMERICA,**

Plaintiff,

v.

**VARIOUS GOLD, SILVER AND COINS,**  
*et al., in rem,*

Defendants,

**and**

**JAMES G. COLE**, an individual,  
**JAMES G. COLE, INC.**, a corporation, and  
**SONIC LIFE.COM, LLC**, formerly known  
as **SONIC HEALTH SYSTEMS, LLC**, a  
limited liability company,

Claimants.

Case No. 3:11-cv-01179-SI (Lead Case)

Case No. 3:11-cv-01424-SI

**OPINION AND ORDER**

S. Amanda Marshall, United States Attorney, Katherine C. Lorenz and Allan M. Garten,  
Assistant United States Attorneys, United States Attorney's Office, District of Oregon, 1000  
S.W. Third Avenue, Portland, OR 97204. Attorneys for Plaintiff.

Michael A. Cox, Law Office of Michael A. Cox, 7420 S.W. Bridgeport Road, Suite 100, Tigard,  
OR 97224; John J.E. Markham, II, Markham & Read, One Commercial Warf West, Boston, MA  
02110. Attorneys for Claimants.

**Michael H. Simon, District Judge.**

The United States brings this consolidated civil *in rem* forfeiture action against various items of property, referred to as “Defendants.” James G. Cole, James G. Cole, Inc., and Sonic Life.com, LLC (collectively “Claimants”) assert claims to the property, which consist of \$520,000.00 worth of various gold, silver, and coins, \$144,302.68 from Claimants’ business accounts, a Toyota Tacoma truck (or \$17,500, which Claimants have substituted for that truck), and a condominium in California. The Government alleges that these assets are or have been purchased with proceeds of mail fraud or wire fraud relating to the sale of (1) nutritional supplements marketed as Maxam Nutraceuticals (“Maxam”) and (2) a patented, vibrational therapy device known as the “TurboSonic” that emits sonic vibrations. This action is brought under 18 U.S.C. § 981(a)(1)(C), which provides that property constituting or derived from proceeds traceable to a “specified unlawful activity” is subject to forfeiture to the United States, and 18 U.S.C. §§ 1956(c)(7) and 1961(1), which provide that mail fraud and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343 constitute such “specified unlawful activities.” This Opinion and Order addresses all pending motions *in limine* and other evidentiary matters.

**DISCUSSION****A. The Government’s Motions *in Limine***

- 1. The jury should be instructed that they are permitted, but not required, to draw an adverse inference based on Daniel George’s refusal to testify to the substantive issues at stake in the case.**

*Withdrawn. See Dkt. 116.*

- 2. Motion to exclude evidence of Claimants’ compliance efforts after the date of the search warrant and to provide an instruction that the jury should disregard evidence of separate FDA investigations against Claimants.**

*DENIED IN PART (CONCERNING THE EXCLUSION OF CERTAIN EVIDENCE) AND GRANTED IN PART (CONCERNING THE REQUEST FOR JURY INSTRUCTIONS).*

At various times, the U.S. Food and Drug Administration (“FDA”) has sent “warning” letters to Claimants, advising them about alleged misrepresentations on Claimants’ websites. *See, e.g.*, Ex. 4 (2003 letter) , Ex. 5 (2004 letter), and Ex. 6 (2010 letter). On April 7, 2011, the Government, pursuant to warrant, searched Claimants’ home and business premises. The Government asserts that after these searches, Claimants made “Herculean efforts” to clean up their business and comply with FDA regulations. According to the Government, Claimants’ efforts were unsuccessful, and on September 12, 2013, the Government filed a complaint in a different but related case, seeking permanent injunctive relief. The Government moves to exclude any evidence of “Claimants’ purported efforts to comply with FDA regulations after the searches on April 7, 2011” as well as any evidence of related FDA administrative actions. The Government relies upon Fed. R. Evid. (“FRE”) 403 and argues that such evidence would be analogous to evidence by a defendant in a fraud case that the defendant intended someday to repay the fraud victim. The Government’s analogy is misplaced, and the evidence of Claimants’ purported compliance efforts will not be excluded. To that extent, the Government’s motion *in limine* is DENIED IN PART. The jury will, however, be appropriately instructed regarding how any evidence of administrative actions should be considered, if at all. To that extent, the motion is GRANTED IN PART.

The Government seeks to prove at trial that Claimants’ scheme to defraud included both false representations and material omissions, including failing to “disclose the receipt of warning letters from the FDA informing them that the products sold by Maxam . . . violated FDA law.” Gov’t Trial Brief at 13-14, Dkt. 91. In particular, the warning letter dated October 12, 2010, states that Maxam products were “offered for conditions which are not amendable to self-diagnoses and treatment by individuals who are not medical practitioners, such as, but not

limited to, autism, Alzheimer's disease, heavy metal toxicity, uterine fibroids, mood disorders, impotence, asthma, diabetes, and infections including herpes." Ex. 6. The FDA's letter is relevant both because it was not disclosed to the potential customers and because it places Claimants on notice of their allegedly false or misleading statements.

Similarly, what Claimants did after receiving these letters also may be relevant to Claimants' attempt to rebut the Government's claim of fraud, especially concerning the required element of fraudulent intent. The fact that the Government executed a search warrant on April 7, 2011, does not change this analysis. The execution of a search warrant, by itself, does not prove that Claimants engaged in any wrongdoing. Moreover, the existence of the earlier letters from the FDA, which the Government offers in evidence, shows that Claimants were not unaware of the Government investigations before April 7, 2011. Thus, the fact that the Government decided to execute search warrants on that date has minimal evidentiary significance, and Claimants' actions and responses upon receiving the various FDA letters are relevant and admissible.

**3. Motion to exclude evidence regarding the number of federal agents who executed the April 7, 2011 warrants and the number of boxes of documents and other evidence seized during that search.**

GRANTED.

The parties agree that the search warrants issued and executed should not be referenced during trial and that they will specifically instruct their witnesses not to do so. *See* Dkt. 116.

**B. Claimants' Motions *in Limine***

**1. Motion to disallow the Government from calling Claimants' witnesses in the Government's case-in-chief.**

*Withdrawn. See* Dkt. 116.

**2. Motion to admit survey evidence.**

GRANTED.

Claimants move to introduce questionnaires sent by Agent Hilary Rickher of the FDA's Office of Criminal Investigation to customers who purchased TurboSonic machines. Claimants offer these questionnaires as evidence that any representations that TurboSonic products were "FDA Certified" or "FDA Approved" had no effect on the customers' use of and satisfaction with these products. The Government responds that the method used in formulating and distributing these questionnaires was not done in a scientific manner, that the evidence gathered cannot be easily aggregated, and that the statements contained within the questionnaire responses constitute inadmissible hearsay.

The FDA sent questionnaires to all TurboSonic customers that Agent Rickher was able to identify, asking these customers about their "experiences with TurboSonic USA and the TurboSonic machine." *See* Cl.'s Ex. 278. This sort of questionnaire is a form of survey evidence. *See* Federal Judicial Center, *Reference Manual on Scientific Evidence*, 405 (3rd ed. 2011) ("*Reference Manual*") (noting that a mail questionnaire is a survey instrument); *see Gibson v. Cnty. of Riverside*, 181 F. Supp. 2d 1057, 1066-69 (C.D. Cal. 2002) (evaluating questionnaires sent out to county residents for reliability and using standards of reliability applicable to survey evidence generally); *see also Pittsburgh Press Club v. United States*, 579 F.2d 751, 758 (3d Cir. 1978). Survey evidence is commonly used, *inter alia*, in cases related to trademark infringement and misleading advertising cases. 1 McCormick On Evid. § 208 (7th ed.); *see also* Suzanne Bonamici, *The Use and Reliability of Survey Evidence in Deceptive Advertising Cases*, 62 Or. L. Rev. 561 (1983) (describing the use of survey evidence and indicia of reliability in Federal Trade Commission false advertising actions).

Survey evidence is "admissible, if relevant, either as nonhearsay or through a hearsay exception." *Prudential Ins. Co. of Am. v. Gibraltar Fin. Corp. of Ca.*, 694 F.2d 1150, 1155 (9th

Cir. 1982). “The proponent must show that the survey was conducted in accordance with generally accepted survey principles and that the results were used in a statistically correct manner.” *Keith v. Volpe*, 858 F.2d 467, 480 (9th Cir. 1988). Thus, in order for the TurboSonic questionnaire responses to be admissible, Claimants must show that the responses are: (a) relevant; (b) reliable; and (c) not excluded under the rule against hearsay. *Id.*

**a. Relevance**

Evidence is relevant if it has any tendency to make a fact of consequence more or less probable than it would be without the evidence. FRE 401. Claimants seek to use the questionnaire responses to show both that Claimants’ alleged misrepresentations and omissions were not material and, accordingly, that the seized assets are not traceable to materially fraudulent statements. The Government must show that the allegedly fraudulent representations or omissions were material. *See United States v. Wood*, 335 F.3d 993, 1000 (9th Cir. 2003). Further, the Government must demonstrate that the defendant property are “proceeds” of mail fraud or wire fraud. 18 U.S.C. § 981(a)(2)(A); *see also United States v. Newman*, 659 F.3d 1235, 1243 (9th Cir. 2011). Claimants contend that “any representation that Claimants’ products were ‘FDA Certified’ or ‘FDA Approved’ had no impact on the customers’ use of an overwhelming satisfaction with the products.” Cl.’s Motions *in Limine*, Dkt. 53 at 5. This evidence relates to the question of materiality. It is, therefore, relevant.

**b. Reliability**

Survey evidence is only admissible if it was obtained “in accordance with generally accepted principles” and “the results were used in a statistically correct manner.” *Keith*, 858 F.2d at 467. Any alleged technical inadequacies with a survey, “including the format of the questions or the manner in which it was taken, bear on the weight of the evidence, not its admissibility.” *Id.* If, however, there are substantial design defects in the survey or its execution is deficient, then

the survey should be completely excluded. *See Harolds Stores, Inc. v. Dillard Dep't Stores*, 82 F.3d 1533, 1544 (10th Cir. 1996); *Pittsburgh Press Club v. United States*, 579 F.2d 751, 759-60 (3d Cir. 1978); *accord Keith*, 858 F.2d at 480. The Ninth Circuit does not have a standard test to determine when a survey is conducted reliably, but the *Handbook of Recommended Procedures for the Trial of Protracted Cases* provides a list of important factors, including:

- (1) The proper universe was selected and examined;
- (2) A representative sample was drawn from that universe;
- (3) The mode of questioning the interviewees was correct;
- (4) The persons conducting the survey were recognized experts;
- (5) The data gathered were accurately reported;
- (6) The sample design, the questionnaire and the interviewing were in accordance with generally accepted standards of objective procedure and statistics in the field of such surveys;
- (7) The sample design and the interviews were conducted independently of the attorneys; and,
- (8) The interviewers trained in this field had no knowledge of the litigation or the purposes for which the survey was used.

Judicial Conference of the United States, *Handbook of Recommended Procedures for the Trial of Protracted Cases*, 25 F.R.D. 365 (1960) (“*Handbook*”). The more modern *Reference Manual* enumerates similar considerations. *Reference Manual* at 373-76.

Claimants argue that the results of Agent Rickher’s questionnaire are reliable, and they refer to her deposition testimony. Agent Rickher testified that the survey was designed by the Government for the purpose of investigating Claimants’ alleged fraud. She testified:

- Q. [Claimants’ Counsel]: And did you believe that this was an objectively stated group of questions just simply aimed at getting the truth?

A. [Agent Rickher]: The truth to the questions I was interested in, yes.

Q. Did you think that you in any way stacked the questions so that they would be more favorable to the government's position in this case than to TurboSonic's position?

A. No.

Q. Did you believe that this questionnaire was made in a way that was calculated to obtain reliable answers?

A. Yes.

\* \* \*

Q. Do you think that the answers are reliable?

A. Yes.

\* \* \*

Q. In connection with that survey, who helped you devise the questions on that?

A. I did, and I believe I also sent them to the attorneys here. Yes, I did send them to the attorneys here.

Q. To be reviewed before they went out?

A. Correct.

Q. And that was a part of what you – part of the basis for you saying that you thought it was a fair survey because the Department of Justice reviewed it, you reviewed it before you went out.

A. Yes.

Cl.'s Motions *in Limine*, Dkt. 104 at 7-8. In response, the Government argues that the questionnaires were not conducted in a scientific manner and cannot be aggregated.

The Court considers both the representativeness of the sample and the sample design in order to ensure that “the questionnaires and the manner of interviewing meet the standards of objective surveying and statistical techniques.” *Gibson*, 181 F. Supp. 2d at 1067-68. There is no



apparent error regarding the representativeness of the sample because Agent Rickher sent the survey to all individuals she believed had purchased the TurboSonic machine. Further, the design of the TurboSonic questionnaire is sufficiently reliable. It was designed for FDA investigative purposes—the cover letter to TurboSonic customers stated that the questionnaire was from the criminal investigations office of the FDA and that the office was investigating sales of TurboSonic products. This disclosure is not a sufficient flaw to exclude the questionnaire responses, unless the respondents had a vested interest in the lawsuit and putting them on notice of the investigation created an inherent bias in their responses. *See Gibson*, 181 F. Supp. 2d at 1069; *Pittsburgh Press*, 579 F.2d at 759-60. The Government has not come forward with any such evidence showing that the TurboSonic customers had any such bias.

In addition, Agent Rickher's involvement in formulating the questions is not akin to a litigating attorney specifically designing and implementing a questionnaire that the litigating attorney then wishes to offer over the objection of the opposing party. *See Gibson*, 181 F. Supp. 2d at 1068; *Pittsburgh Press*, 579 F.2d at 756 n.7. Here, it is the opposing party that seeks to offer the responses to the questionnaire.

Finally, the Government does not explain how Agent Richker's methodologies were "not conducted in a scientific manner." Dkt. 112 at 5. The survey seems to have been designed to elicit honest responses from all known TurboSonic customers. Many of the questions were open-ended, giving questionnaire respondents "fewer hints about expected or preferred answers." *Reference Manual*, at 392. To the extent the Government has specific arguments about the "format of the questions" or the "manner in which the [questionnaire] was taken," those allegations "bear on the weight of the evidence, not its admissibility." *Keith*, 858 F.2d at 467. Thus, the TurboSonic questionnaire responses are sufficiently reliable.

**c. Hearsay**

Hearsay is a statement, other than one made by the declarant while testifying at trial or hearing, offered in evidence to prove the truth of the matter asserted. FRE 801(c). One question on Agent Rickher's questionnaire asks: "The TurboSonic is not FDA-Approved. Would you have wanted to know that information before deciding whether to buy a TurboSonic." Cl.'s Ex. 278. Claimants offer the responses to this question to show that the "FDA Certified" and "FDA Approved" statements made in connection with the TurboSonic product had no bearing on the TurboSonic customer's purchase of the machine. Cl.'s Motions *in Limine*, Dkt. 104 at 5. The questionnaire also asks: "Were you satisfied with your purchase?" Cl.'s Ex. 278. Claimants offer the responses to this question to show the customer's "overwhelming satisfaction with the products." Cl.'s Motions *in Limine*, Dkt. 104 at 5. Thus, Claimants seek to use these responses to prove the truth of the matters asserted, namely that the respondents did not want to know any additional information and that they were satisfied with their purchase. Thus, these responses are hearsay and thus are inadmissible unless a hearsay exception applies.

Claimants argue that the questionnaire responses fall under the following exceptions to the rule against hearsay: (i) the state of mind exception under FRE 803(3); (ii) the residual exception under FRE 807; (iii) the public records exception under FRE 803(8); and (iv) the present sense impression exception under FRE 803(1).

**i. State of Mind – FRE 803(3)**

FRE 803(3) provides an exception to the rule against hearsay for a "statement of the declarant's then-existing state of mind (such as motive, intent, or plan) or emotional, sensory, or physical condition (such as mental feeling, pain, or bodily health), but not including a statement of memory or belief to prove the fact remembered or believed unless it relates to the validity or terms of the declarant's will." Generally, surveys that ask about the content of an advertisement

and the impressions with which a customer was left “are classic states of mind” under Rule 803(3). *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 227 (2d Cir. 1999). In order to satisfy the requirements under this exception, the questions must specifically “poll individuals about their presently-existing states of mind.” *Id.* at 228.

The TurboSonic questionnaires are best understood as probative of the survey respondents’ opinions of TurboSonic products at the time that the respondents filled out the survey. The basic premise of this interpretation is that “the evidence is introduced to prove that people [had] certain opinions, not to prove the truth of what is perceived in those opinions.” Bonamici, *Reliability of Survey Evidence*, *supra*, at 578 n. 97. Therefore, the evidence is admissible under FRE 803(3) as an exception to the rule against hearsay.

The Court notes, however, that some of the questions are phrased in the past-tense, which could be interpreted as falling within the exclusion to the state of mind exception. For example, the exclusion would be relevant if one understood the response to the question “[w]ere you satisfied with your purchase?” as a statement of memory or belief being used to prove the fact remembered or believed. Cl.’s Ex. No. 278; FRE 803(3). There is some question on this issue because the questions were not all phrased in either the past-tense or present-tense. In light of the context of the entire survey, the questions are sufficiently probative of the survey respondent’s state of mind at the time they filled out the questionnaire. Nonetheless, the Court also finds an alternative basis of admissibility in the residual hearsay exception.

## **ii. Residual Hearsay Exception – FRE 807**

Survey evidence is often admitted in evidence under FRE 807, which is the “catchall” exception to the hearsay rule. Under this rule, a hearsay statement is not excluded if:

- (1) the statement has equivalent circumstantial guarantees of trustworthiness;
- (2) it is offered as evidence of a material fact;

(3) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts; and

(4) admitting it will best serve the purposes of these rules and the interest of justice.

FRE 807(a). In order for the statement to be admissible, the proponent must give “an adverse party reasonable notice of the intent to offer the statement and its particulars.” FRE 807(b). That has been done in this case. Thus, “the two main considerations affecting admissibility” under Rule 807 are “trustworthiness and necessity.” C. Mueller & L. Kirkpatrick, *5 Federal Evidence* § 8:143 (3d ed.).

As discussed above, the reliability of the TurboSonic questionnaire responses has been sufficiently shown. Trustworthiness, which is closely aligned with reliability, depends on:

- (a) properly defining the “universe” of people whose opinions matter with respect to the subject of the litigation;
- (b) selecting a representative sample from this universe;
- (c) framing questions that are clear, simple, and nonleading;
- (d) following sound interview procedures;
- (e) accurately recording the gathered data;
- (f) following proper statistical methods in analyzing the data; and
- (g) protecting objectivity by keeping the polling process separate from litigation.

*Id.* None of the factors discussed above provide a basis to find that the TurboSonic questionnaire responses are untrustworthy—all known TurboSonic customers were sent questionnaires and there has been no representative sampling or data analysis. Further, although the cover letter to the questionnaires noted that TurboSonic was subject to investigation, the potential for bias would not be in the proponents’ (Claimants’) favor. As already discussed, Agent Rickher

explained in her testimony that the questions were framed in such a way as to elicit truthful and accurate responses.

In any survey, there is always the danger that the respondents are insincere. *See, e.g., Zippo Mfg. Co. Rogers Imports, Inc.*, 216 F. Supp. 670, 684 (S.D.N.Y. 1963). Here, we are not even certain that the people completing the surveys correctly identified themselves. That concern, however, appears to be more speculative than proven.

In this case, the questionnaires required respondents to place at the top of their responses their name, address, phone number, and email address. The Government has not presented any evidence showing that the individuals listed as filling out the surveys were not the actual respondents. The Government has been provided with sufficient “reasonable notice” to seek and offer such evidence to demonstrate a lack of trustworthiness. *See* FRE 807(b). Unless and until such evidence is provided, however, the Court finds that the survey responses are sufficiently trustworthy.

The Court next considers the necessity of survey evidence by comparing “the probative value of the survey with the evidence, if any, which as a practical matter could be used if the survey were excluded.” *Zippo*, 216 F. Supp. at 683. The fact that the survey evidence is the only available survey of all known TurboSonic customers weighs in favor of admissibility. *Cf. Keith*, 858 F.2d at 480 (admitting survey evidence that was more recent than older collected data). Moreover, as in *Zippo*, asking hundreds of known customers to testify at court is “obviously impractical.” 216 F. Supp. at 684. Given these considerations, the questionnaire responses meet the necessity prong of FRE 807.

In sum, the court finds the TurboSonic questionnaire responses fall within the residual hearsay exception.

### iii. Public Records – FRE 803(8)

Claimants also argue that the TurboSonic questionnaire responses should be admissible under the public records exception: first, because they are from “a matter observed while under a legal duty to report” and second, because they are “factual findings [in a civil case] from a legally authorized investigation.” FRE 803(8)(A)(ii)-(iii). Neither exception applies.

Regarding FRE 803(8)(A)(ii), the survey respondents are third parties, not government employees under a legal duty to report. Moreover, Agent Rickher made clear in the cover letter that any responses were voluntarily. *See* Cl.’s Ex. 278. The scope of this exception “reaches records made by one official that embody information provided by another in the course of his duties.” C. Mueller & L. Kirkpatrick, 4 *Federal Evidence* § 8:88 (3d ed.). As such, this exception “generally does not pave the way for official records to prove conclusions resting on statements by outsiders or to prove what such outsider statements themselves assert.” *Id.* Because the survey responses are “statements by third parties who are not government employees,” they may not be “admitted pursuant to the public records exception.” *United States v. Morales*, 720 F.3d 1194, 1202 (9th Cir. 2013); *see also United States v. Pazsint*, 703 F.2d 420, 424 (9th Cir. 1983) (“It is well established that entries in a police report which result from the officer’s own observations and knowledge may be admitted but that statements made by aliens and reported by third persons under no business duty to report may not.”).

Regarding FRE 803(8)(A)(iii), the survey responses are not “factual findings” from a legally authorized investigation. This exception requires that the public record be based on an investigation “authorized by law” and provide “factual findings.” FRE 803(8)(A)(iii). Although Agent Rickher was authorized to investigate alleged fraud committed by Claimants, the survey responses themselves are not factual findings.

“The animating force behind this provision is the view that public officials have expertise in their areas of responsibility that enables them to evaluate information, resolve conflicting indications, and reach factual conclusions that are trustworthy and merit respect.” C. Mueller & L. Kirkpatrick, 4 *Federal Evidence* § 8:89 (3d ed.). Agent Rickher at no point prepared any “report” about the survey evidence that constitutes a “factual finding.” *Cf. United States v. Cent. Gulf Lines, Inc.*, 974 F.2d 621, 625 (5th Cir. 1992) (admitting “survey reports” prepared by independent surveyors hired by a government agency with the duty of report, under FRE 803(8)(A)(iii)). In *Keith*, the Ninth Circuit upheld the district court’s admission into evidence a *summary* of forms completed the California Department of Transportation (“Caltrans”). 858 F.2d at 481. In that case, pursuant to a court order, Caltrans agents requested information from relevant displaced households. *Id.* That information was turned into summary form and a chart. *Id.* In contrast with *Keith*, Agent Rickher here did not summarize or analyze the responses from TurboSonic customers or make any “factual findings.”

**i. Present Sense Impression – FRE 803(1)**

Claimants’ final argument is that the questionnaire responses are admissible under FRE 803(1) as a “statement describing or explaining an event or condition, made while or immediately after the declarant perceived it.” At “the heart of the exception” is the “idea of immediacy.” C. Mueller & L. Kirkpatrick, 4 *Federal Evidence* § 8:67 (3d ed.). Therefore, in order for the responses to fall within this exception, the statements must be made “while or immediately after” the purchasers perceived an event or condition they are describing. *See United States v. Orm Hieng*, 679 F.3d 1131, 1142 (9th Cir. 2012). The responses do not appear to satisfy this condition.

**3. Motion to preclude allegations of violations of FDA regulations**

*RULING RESERVED.*

Claimants move to exclude all testimony regarding alleged violations of FDA regulations by the Claimants. They argue that this testimony is irrelevant to the pending civil *in rem* forfeiture action. The Government responds that the testimony regarding alleged non-compliance with FDA regulations is relevant to establishing that Claimants perpetrated a scheme to defraud in their sale of Maxam and TurboSonic products. In particular, the Government argues that alleged improper manufacturing practice violations, bacteria in the products, Claimant's publication of customer testimonials, and claims that the products are "FDA-Approved" all represent material misrepresentations and omissions. (The Government adds that it will instruct Agent Rickher to not testify regarding her personal belief as to whether Claimants committed regulatory violations in addition to committing fraud.)

As noted in the Court's ruling on the Government's motion *in limine* No. 2, and Claimants' motion *in limine* No. 2, an allegation that Claimants made material misrepresentations is a *prima facie* element of mail fraud or wire fraud. Any reference to FDA regulations by any party during a witness's testimony require fact-specific analysis and ruling. The Court agrees with Claimants that the Government should not assert or argue that Claimants in fact violated any FDA regulations, and the FDA investigation or regulations should only be referred to when necessary to establish a material fact in this case. The Government responds that it agrees with this conclusion. Thus, the Court reserves ruling on Claimants' motion. To the extent that either party believes that a reference to FDA regulations is improper, that party may object at trial. During opening statements, however, there should be no reference to any FDA regulations.

### **C. Use of Pre-Admitted Trial Exhibits**

Pre-admitted trial exhibits may be used by any party at any time during trial from opening statement through the conclusion of Plaintiff's rebuttal case. A pre-admitted trial



exhibit, however, may not be used during closing argument and will not be available for use by the jury during deliberations unless specifically used and referred to during trial at some point between opening statement and the conclusion of Plaintiff's rebuttal case. *See* FRE 611(a)(1).

#### **D. Claimants' Objections to the Government's Trial Exhibits**

##### **1. Pre-Admitted Trial Exhibits**

The following trial exhibits are pre-admitted and received in evidence without objection: Exhibits 1, 3, and 7-95.

##### **2. Additional Pre-Admitted Trial Exhibits**

The following trial exhibits are pre-admitted and received in evidence over Claimants' objections: Exhibits 4, 5, and 6.

##### **3. Rulings on Claimants' Objections to Government's Trial Exhibits**

Ex. 2            *RULING RESERVED*. The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 4            *OVERRULED*. This letter, dated February 28, 2003, is part of the Government's evidence of fraud. Although "proof of a scheme or artifice to defraud does not require the proof of the making of any *specific* false statement," the Government may provide such evidence to the jury to prove its case-in-chief. *United States v. Omer*, 395 F.3d 1087, 1089 (9th Cir. 2005) (per curiam). The fact that this letter is more than a decade old does not undermine its probative value to the extent that the Government seeks to prove that Claimant's scheme to defraud spans that same period of time.

Ex. 5            *OVERRULED*. Claimant's objection to this letter, dated March 11, 2004, is overruled for the reasons explained in connection with Ex. 4.

Ex. 6            *OVERRULED*. Claimant's objection to this letter, dated October 12, 2010, is overruled for the reasons explained in connection with Ex. 4.

## **E. Government's Objections to Claimants' Trial Exhibits**

### **1. Pre-Admitted Trial Exhibits**

The following trial exhibits are pre-admitted and received in evidence without objection: Exhibits 201-231, 233, 235-241, and 262-276.

### **2. Additional Pre-Admitted Trial Exhibits**

The following trial exhibits are pre-admitted and received in evidence over the Government's objections: 234, 242-258, and 278.

### **3. Rulings on Government's Objections to Claimants' Trial Exhibits**

Ex. 232        *RULING RESERVED.* The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 234        *OVERRULED.*

Ex. 242-258   *OVERRULED.* See Court's ruling on Government's motion *in limine* No. 2.

Ex. 259        *RULING RESERVED.* The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 260        *RULING RESERVED.* The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 261        *RULING RESERVED.* The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 277        *RULING RESERVED.* The Court will consider the admissibility of this exhibit if offered at trial.

Ex. 278        *OVERRULED.* See Court's ruling on Claimants' motion *in limine* No. 2.

**F. Claimants' Objections to Government's Lay Witnesses**

**1. Claimants' objections to certain testimony by Joseph Pontoriero.**

The Government agrees to remove the comment by counsel at 18:12. All other objections are *OVERRULED*. See FRE 803(4)(A).

**2. Claimants' objections to certain testimony by Hilary Rickher**

It appears that Claimants' objections to certain testimony by Hilary Rickher may have been resolved either by agreement of the parties, *see* Dkt. 116, or by the Court's rulings on the pending motions *in limine*. To the extent that Claimants have additional objections to the testimony of Agent Rickher, Claimants may present those objections to the Court after conferring further with the Government.

**3. Claimants' objections to certain testimony by Dr. Tom Brueggemeyer**

*OVERRULED*. If, however, Claimants have not previously taken the deposition of Dr. Brueggemeyer in this action and now wish to do so, the Government shall make him available for deposition at least one business day before calling him as a witness.

**4. Claimants' objections to certain testimony by Caroline Stites**

The Government agrees to remove the following testimony: 32:1-4, 34:16-35:11, 46:21-47:21, 48:6-49:7, and 52:16-53:6. All other objections are *OVERRULED*.

**5. Claimants' objections to certain testimony by Daniel George**

Claimants originally objected to any reference to Mr. George's refusal to answer questions at his deposition. In light of the Government's withdrawal of its motion *in limine* no. 1 (*see* Dkt. 116), the Court assumes that Claimants' objection is moot. Claimants may inform the Court if this assumption is incorrect.

**6. Claimants' objections to certain testimony by Won Koo Yoon**

The Government agrees to remove the following testimony: 35:23-25, 38:13-27, and 47:2-3. All other objections are *OVERRULED*.

**7. Claimants' objections to certain testimony of witnesses employed by Claimants**

*Withdrawn. See Dkt. 116.*

**G. Claimants' Objections to Government's Expert Witnesses**

**1. Dr. Robert Temple**

Claimants argue that references in Dr. Temple's report that contend that TurboSonic or Maxam products are "dangerous" go beyond the scope of this lawsuit. In particular, Claimants argues that because this is a civil *in rem* forfeiture case based on fraud and that at issue is whether the statements were knowingly false, not whether they were "dangerous."

*OVERRULED.* Whether Claimants failed to disclose that their products were dangerous, or falsely represented that they were safe, is relevant to the Government's claim of fraud.

**2. Dr. Corey Hilmas**

Claimants object to various statements within Dr. Hilmas's report. *See Dkt. 93-3.* The Court addresses each in turn.

- a. Dr. Hilmas's statement that Maxam and TurboSonic product promotion are "misleading and irresponsible and not based upon science" go beyond this civil *in rem* forfeiture case based on fraud. Dkt. 93-3 at 4.**

*OVERRULED.*

- b. Dr. Hilmas's comment that a claim or treatment is "misleading" is a question for the jury and beyond the scope of Dr. Hilmas's expertise. Dkt. 93-3 at 4.**

*OVERRULED. See FRE 704(a).*

- c. **Dr. Hilmas’s statement that if there was a treatment for autism, an Investigational New Drug application would have been filed, basic science research would have been initiated, and a Nobel Prize would have been issued to the discoverer, is speculative and beyond Dr. Hilmas’s expertise. Dkt. 93-3 at 4-5.**

*OVERRULED.*

- d. **Dr. Hilmas’s statement that “[c]ustomers are also not told that prescription drugs and analogs of those drugs are being used to produce this unidentified peptide” goes beyond the expertise of a microbiologist and that there is a lack of foundation for his assertion. Dkt. 93-3 at 6.**

*OVERRULED.*

- e. **Dr. Hilmas’s statement that he does not believe Claimants used gold to make Maxam products is not a proper subject of expert opinion and there is no basis for his asserted belief. Dkt. 93-3 at 6.**

*RULING RESERVED.* The Court will consider the admissibility of this testimony after an appropriate foundation has been laid at trial.

- f. **Dr. Hilmas’s statement that Claimants would have applied for a patent if gold was used to create the Maxam products is beyond the scope of Dr. Hilmas’s expertise. Dkt. 93-3 at 6.**

*RULING RESERVED.* The Court will consider the admissibility of this testimony after an appropriate foundation has been laid at trial.

- g. **Dr. Hilmas’s comment that Mr. Cole’s testimony regarding “a protectant peptide reminds me of descriptions of carpet baggers” is not sound expert opinion based on microbiology. Dkt. 93-3 at 6.**

*SUSTAINED.*

- h. **Dr. Hilmas’s speculation that it is possible that Dan George did not actually use pharmaceutical compounds in the Maxam manufacturing process is guesswork and not proper expert opinion. Dkt. 93-3 at 8.**

*RULING RESERVED.* The Court will consider the admissibility of this testimony after an appropriate foundation has been laid at trial.

- i. Dr. Hilmas’s statement as to what is “required by law” is beyond the scope of his expert opinion. Dkt. 93-3 at 8.**

*RULING RESERVED.* The Court will consider the admissibility of this testimony after an appropriate foundation has been laid at trial.

- j. Dr. Hilmas’s statement that the bacteria found by the FCC lab in the Maxam products were intentionally included in the Maxam products is speculative. Dkt. 93-3 at 9.**

*RULING RESERVED.* The Court will consider the admissibility of this testimony after an appropriate foundation has been laid at trial.

- k. Dr. Hilmas’s statement that “[t]he use of an ‘unknown’ laboratory under unknown conditions by a convicted felon is cause for even greater concern” is irrelevant to establish a basis for the showing of fraud. Dkt. 93-3 at 9.**

*OVERRULED.*

#### **H. Government’s Objections to Claimants’ Lay Witnesses**

- 1. Compliance with the Court’s Trial Management Order Instructions Regarding Narrative Witness Statements.**

*Withdrawn. See Dkt. 116.*

- 2. Government’s objections to certain testimony by Jeanne Suiste**

*OVERRULED.*

- 3. Government’s objections to certain testimony by Ginnie Mooney**

*OVERRULED.*

- 4. Government’s objections to deposition designation testimony of Dr. Jennifer Brzezinski**

*SUSTAINED.*

- 5. Government’s objections to certain substantive deposition cross-designations**

- a. Joanne Kissler:**

*Withdrawn. See Dkt. 116.*

**b. Beverly Biondi:**

*Withdrawn. See Dkt. 116.*

**c. Joseph Pontoriero:**

*Withdrawn. See Dkt. 116.*

**d. Andrew Thompson:**

*Withdrawn. See Dkt. 116.*

**CONCLUSION**

The parties' motions *in limine* and other evidentiary matters raised in Dkts. 98, 102, 103, 104, 110, 111, 112, 116, and 117 are GRANTED IN PART and DENIED IN PART as set forth in this Opinion and Order. The following trial exhibits are pre-admitted and received in evidence: Government Exhibits 1 and 3-95 and Claimants Exhibits 201-231, 233-258, 262-276, and 278. The Court reserves ruling on the following trial exhibits until offered at trial: Government Exhibit 2 and Claimants Exhibits 232, 259-261, and 277.

**IT IS SO ORDERED.**

DATED this 30th day of October, 2013.

/s/ Michael H. Simon  
Michael H. Simon  
United States District Judge